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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SERENA KWAN; an Individual, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

vs.

SANMEDICA INTERNATIONAL, LLC, a Utah Limited Liability Company and SIERRA RESEARCH GROUP, LLC, a Utah Limited Liability Company,

Defendants.

Case No. 3:14-CV-03287-MEJ

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS**

Date: November 13, 2014
Time: 10:00 a.m.
Courtroom: B -15th Floor
Judge: Hon. Maria-Elena James

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Defendant San Medica International, LLC ("San Medica") and Defendant Sierra Research Group LLC ("Sierra Research"), pursuant to Fed. R. Civ. Pro. 12(b)(6), respectfully submit this Memorandum of Points and Authorities in support of this Motion to Dismiss (the "Motion") all claims asserted by Serena Kwan ("Plaintiff").[1]

## I. INTRODUCTION AND BRIEF STATEMENT OF ISSUES TO BE DECIDED

Plaintiff's First Amended Complaint (the "FAC"), which purports to state claims under California's unfair competition and consumer protection statutes, should be dismissed for failure to state a claim for three reasons.

**First**, the FAC rests entirely on an impermissible substantiation claim. It alleges that Defendants' study on which the advertisements at issue are based is unsubstantiated by competent scientific evidence. Aside from alleging that the advertising claims lack proper substantiation, the FAC fails to allege any facts showing that the advertisements are false or misleading in and of themselves. Courts have repeatedly held these types of causes of action— alleging a lack of substantiation of an advertising representation—may not be asserted by private litigants and are not sufficient to state a claim for violation of California's Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq.*) (the "UCL") or California's Consumers Legal Remedies Act (Cal. Civ. Code § 1750, *et seq.*) (the "CLRA").

**Second**, Plaintiff's allegations, all of which concern the contents of a study referenced, incorporated into and integral to the FAC, flatly contradict the study.[2] The FAC's allegations rest on the demonstrably false statement that Defendants have relied on a flawed study in claiming that the SeroVital product (the "Product") yields a 682% mean increase in HGH levels.

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[1] Simultaneously with the filing of this Motion, Sierra Research, pursuant to Fed R. Civ. Pro. 12(b)(2), has filed a motion to dismiss this case against it for lack of personal jurisdiction. *See Northern Laminate Sales, Inc. v. Matthews*, 249 F.Supp.2d 130, 137 (D.N.H. 2003) (rejecting argument that defendant waived personal jurisdiction defense because he included an alternative request to dismiss under Rule 12(b)(6)). Collectively, San Medica and Sierra Research are referred to herein as "Defendants."

[2] Because the study is integral to and referenced throughout the FAC, the Court may consider the actual study documents in resolving the Motion. *See Knievel v. ESPN,* 393 F.3d 1068, 1076 (9th Cir. 2005).

Plaintiff's attack on Defendants' study, however, is belied as implausible under a review of, and in fact simply contradicts, the contents of the study. The study reveals Plaintiff's allegations are unfounded, conclusory, and flat wrong, rendering Plaintiff's claims against Defendants legally implausible and subject to dismissal pursuant to Rule 12(b)(6).

**Third**, the FAC fails to show that Defendants did not to rely on competent scientific evidence, the governing standard in cases involving scientific substantiation of advertising claims.

Dismissal of the entire action is appropriate.

## II. STATEMENT OF RELEVANT ALLEGED FACTS

Framed as a putative class action, Plaintiff's FAC imprecisely alleges that Defendants manufacture, market, sell and distribute SeroVital, an over-the-counter amino acid supplement. Plaintiff claims that Defendants have engaged in false advertising by virtue of "an extensive, widespread, comprehensive and uniform nationwide marketing campaign. Defendants manufacture, market, sell and distribute, an over-the-counter amino acid supplement." Plaintiff further alleges that Defendants, through "an extensive, widespread, comprehensive and uniform nationwide marketing campaign" make certain "growth hormone representations, including, (1) SeroVital is "clinically tested" to boost human growth hormone ("HGH") by a mean of 682% for those who take it. Plaintiff further alleges that these growth hormone representations are false, misleading, and reasonably likely to deceive the public. Plaintiff seeks damages based upon the allegation that Defendants' allegedly deceptive growth hormone representations, have duped consumers, including Plaintiff and members of the proposed Class, into purchasing what they believed to be a product that was shown in clinical testing to increase human growth hormone by a mean of 682%, when the sole study on which the HGH benefit claim is based is not credible scientific support.

## III. ARGUMENT

### A. Standards Applicable to This Motion.

When determining whether a complaint states a claim upon which relief can be granted, although the court accepts the truth of all alleged *facts* in the complaint, "courts 'are not bound to accept as true a legal conclusion couched as a factual allegation.'" *Bell Atlantic Corporation v.*

*Twombly*, 550 U.S. 544, 570 (2007) (citation omitted). Moreover, the Supreme Court has held that even where a complaint contains non-conclusory, factual averments, a complaint will only survive a motion to dismiss if it contains "enough facts to state a claim to relief that is ***plausible*** on its face." *Id.* (emphasis added). As the Supreme Court has stated:

> Two working principles underlie our decision in *Twombly*. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not "show[n]"—"that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).
>
> ***
>
> In keeping with these principles a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

*Ashcroft v. Iqbal*, 556 U.S. 662, 679–680 (2009) (citations omitted).

The policy behind *Twombly*'s plausibility standard is to expose defects in a case early in the process, "at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558. Implementation of the *Twombly* standard affirms that "a district court must retain the power to insist upon some specificity in pleading" before allowing potentially costly cases to proceed. *Id.* (citation omitted).

Applying this standard to this case, Plaintiff must allege sufficient facts to "raise a right to relief above the speculative level" and "nudge[] [its] claims across the line from conceivable to plausible." *Id.* at 555, 570. In order to survive this Motion, therefore, the factual, non-conclusory

allegations of each of the individual claims must set forth "more than a sheer possibility that [Defendants] acted unlawfully." *Iqbal*, 556 U.S. at 678. Plaintiff's claims fail to meet this standard, and should be dismissed without leave to amend.

**B. There Is No Private Right Of Action For Substantiation Claims**

Fatally, the FAC is based entirely on allegations for which there is simply no private right of action—allegations concerning a purported lack of scientific substantiation for the advertising claims related to the Product. Courts have repeatedly held that actions based on such allegations are not actionable by private individuals. *See Stanley v. Bayer Healthcare LLC*, 11CV862-IEG BLM, 2012 WL 1132920, *3-4 (S.D. Cal. Apr. 3, 2012) ("Private individuals may not bring an action demanding substantiation for advertising claims" and "alleged lack of substantiation does not render claims false and misleading under the UCL or CLRA."); *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Cal.App. 4th 1336, 1342 (2003); *Chavez v. Nestle USA, Inc.*, No. CV-09-9192-GW-CW, 2011 WL 2150128, at *5 (C.D.Cal. May 19, 2011) *aff'd in part, rev'd in part on other grounds,* 511 F. Appx. 606 (9th Cir. 2013) ("false advertising claims cannot be based upon a lack of substantiation"); *Dorfman v. Nutramax Laboratories, Inc.*, No. 13-cv-0873-WQH (RBB), 2013 WL 5353043, at *11 (S.D. Cal. Sept. 23, 2013); *Fraker v. Bayer Corp*, 2009 U.S. Dist. LEXIS 125633 (E.D. Cal. Oct. 2, 2009); *Hughes v. Ester C Co.*, 930 F.Supp.2d 439, 457 (E.D.N.Y. 2013); *Johns v. Bayer Corp.*, 2013 U.S. Dist. LEXIS 51823, 105-106 (S.D. Cal. Apr. 10, 2013); *See Eckler v. Wal-Mart Stores, Inc.*, 2012 U.S. Dist. LEXIS 157132, 9-10 (S.D. Cal. Oct. 31, 2012); *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Cal. App. 4th 1336, 1345-1346 (2003) ("The Legislature indicated an intent to alter the burden of substantiating advertising claims only with respect to prosecuting authorities"). *Cf.* Cal. Bus. & Prof. Code § 17508 (giving power to demand substantiation for advertising only to "the Director of Consumer Affairs, the Attorney General, any city attorney, or any district attorney").

Because there is no private cause of action for false advertising claims based on lack of substantiation, a private litigant seeking to assert false advertising or unfair competition claims must clearly demonstrate, with affirmative evidence, the advertising claims are false in and of

themselves. "Under current California law, [a] plaintiff in a false advertising action has the burden of producing evidence to prove the allegations of the complaint that the challenged advertising is false or misleading." *King Bio*, 107 Cal. App. 4th at 1345-1346. "The falsity of the advertising claims may be established by testing, scientific literature, or anecdotal evidence." *Id.* at 1348. "This limitation prevents undue harassment of advertisers and is the least burdensome method of obtaining substantiation for advertising claims." *Id.* at 1338.

The FAC asserts two causes of action, one alleging false advertising in violation of the UCL and the other alleging that the purportedly false advertising violates the CLRA. Under both of these causes of action, Plaintiff bears the burden at this stage to affirmatively plead facts showing specifically how the Product advertising is false or misleading. The FAC fails to do this.

The FAC does not contain a single alleged fact based on "testing, scientific literature, or anecdotal evidence" claiming that the advertisements are false or misleading. *King Bio*, 107 Cal. App. 4th at 1348. Rather, the FAC rests entirely on allegations that the advertising claims lack substantiation because the underlying study is allegedly flawed. The FAC alleges:

- ". . . the study Defendants cite to is clearly flawed and does not and cannot serve as the basis for the representations made by Defendants." [FAC, ¶ 1.]
- ". . . the sole study on which the HGH benefit claim is based is not credible scientific support for the '682% MEAN INCREASE . . . ' representation. Further, there is absolutely no support from any credible scientific source that any of the ingredients in SeroVital, alone or in combination, in the dosages found in the Product, provide the represented growth hormone level." [*Id.*, ¶¶ 3, 23.]
- "The sole study on which the '682% . . . 'representation is based does not constitute credible scientific support for the claim. In fact, there is absolutely no support from any credible scientific source that any of the ingredients in SeroVital . . . provide the represented growth hormone level." [*Id.*, ¶ 8.]
- "The sole study purportedly supporting Defendants' HGH benefit representations is riddled with so many flaws that it is completely unreliable." [*Id.*, ¶ 14.]
- "Defendants do not rely on a study *report* of the type that would be accepted by any credible, peer-reviewed scientific journal. Rather, Defendants rely on a published study *abstract* . . . ." [*Id.*, ¶ 16.]
- "[T]he SeroVital study upon which Defendants rely is not competent and reliable evidence of a '682% MEAN INCREASE IN

SERUM GROWTH HORMONE LEVELS'." [*Id.*, ¶ 17.]

Plaintiff's pleading burden ***is not*** met by alleging the studies on which the advertisements are based are flawed. These allegations ***cannot*** form the basis for actions under the UCL or CLRA because they simply are lack of substantiation claims—they all attack the scientific support for the Product's claims without citing to or alleging that there are studies or other scientific evidence that contradict the scientific support on which Defendants substantiate the advertising claims. The FAC ***does not*** plead plausible facts showing that the advertisements are *false or misleading*, or how they are false or misleading. Plaintiff's failure to do so defeats its claims.

The plaintiff in *Fraker* 2009 U.S. Dist. LEXIS 125633 made the same mistake. There, instead of pleading facts showing why the defendant's advertising was false, the plaintiff merely referenced an FTC case against the defendant that called into question the scientific substantiation for the defendant's claims. In dismissing the plaintiff's claims, the *Fraker* court found that it is not enough to allege that "absence of substantiation of an advertising claim is, itself, falsity or somehow misleading." *Fraker*, 2009 U.S. Dist. LEXIS at 22. Rather,

> [i]f Plaintiff is going to maintain an action against Defendant for false or misleading advertising, then ***Plaintiff will be required to adduce evidence sufficient to present to a jury to show that Defendant's advertising claims with respect to Product are actually false; not simply that they are not backed up by scientific evidence.***

*Id.* at 22-23 (emphasis added).

Similarly, *Chavez v. Nestle USA, Inc.*, WL 2150128, is nearly identical to the case before this Court. In *Chavez*, the plaintiff's second amended complaint alleged causes of action under the UCL and California's False Advertising Law (Cal. Bus. & Prof. Code § 17500, *et seq.*) based on the defendant's alleged deceptive marketing and advertising practices. *Id.* at *1. The court characterized the complaint as "essentially alleging that Defendant's claims about its products are deceptive because they are unsubstantiated." *Id.* Aside from these claims of lack of substantiation, the court noted that there were only "conclusory allegations of affirmative misrepresentations in the [second amended complaint]." *Id.* at 4. Citing *Fraker*, the court held

that "false advertising claims cannot be based upon a lack of substantiation." *Id.* at *5. And, quoting *Fraker*, the court noted that "[i]n short, the government, representing the Federal Trade Commission, can sue an advertiser for making unsubstantiated advertising claims; a private plaintiff cannot." *Id.* (citation omitted).

Indeed, in granting the defendant's motion to dismiss, the court in *Chavez* construed the claim as a lack of substantiation claim because "Plaintiffs do not, for example, allege facts challenging the relationship of DHA and brain development, the role of Vitamin C and zinc in immune function, or of pre-biotic fiber in digestion . . . Plaintiff has not articulated what about that claim is deceptive beside the fact that it is supposedly unsubstantiated." *Id.* at *4. This is the precise situation here. The FAC does not allege any facts showing that Defendants' products do not work or that they do not actually result in the advertised increase in human growth hormone. Rather, the FAC simply alleges that these claims are not substantiated by the supporting studies. This cannot serve as a basis to assert claims under either the UCL or CLRA. *Stanley*, 2012 WL 1132920, at *3-4; *see Eckler*, 2012 U.S. Dist. LEXIS 157132, 9-10.

Plaintiff's FAC suffers the same affliction fatal to the pleadings in *Fraker* and *Chavez*. Plaintiff's allegations merely contend that Defendant's claims are unsubstantiated by appropriate scientific studies. Plaintiff states, in conclusory fashion, that the advertising claims are false. But the FAC's allegations clearly fail to plead a single plausible fact showing exactly why or how these claims are, in fact, false. Tellingly, Plaintiff does not even allege that Plaintiff's own HGH levels were not boosted by 682% as a result of the Product.

The fact that Plaintiff specifically attacks the study itself, and Defendants' reliance on the study, does not change the fact that the FAC is fundamentally claiming lack of substantiation. For example, in *Franulovic v. Coca Cola Co.*, 390 F. App'x 125 (3d Cir. 2010), the plaintiff filed suit based on the allegation that Coca Cola engaged in fraudulent and deceptive marketing under a similar New Jersey consumer protection statute when it advertised Enviga as a calorie-burning drink "based on the results of a short-term scientific study funded by its corporate partners." *Id* at 126. "Challenging the validity of the study, [the plaintiff] sought declaratory and injunctive relief to prevent Coca Cola from marketing Enviga as the 'calorie burner.'" *Id.* When the plaintiff

sought leave to amend its complaint to assert that Coca Cola advertised Enviga as a calorie burning drink without prior substantiation, the district Court denied the motion as futile. *Id.* at 127. In upholding the district court's ruling, the Third Circuit noted: "the District Court correctly held that a New Jersey Consumer Fraud Act claim cannot be premised on a prior substantiation theory of liability." *Id.* at 128. Likewise, Plaintiff's attack amounts to nothing more than an assertion that there is no scientific evidence supporting a product's representations and this assertion alone cannot survive a motion to dismiss. *Chavez*, 2011 WL 2150128 at *5.

It is simply not enough under the law for a private litigant such as Plaintiff to attack the purported lack of scientific substantiation. In sum, "where a private litigant seeks to assert a false advertising claim under the UCL . . . or CLRA, he ***must set forth more than simply an allegation that a product's statements are not supported by credible science***; rather, he must provide a sufficient factual basis in support of such a contention." *Hughes*, 930 F.Supp.2d at 457 (citing *Fraker*, 2009 U.S. Dist. LEXIS 125633) (emphasis added). Because the FAC fails to affirmatively plead any facts alleging that Defendants' claims are false or misleading, but instead seeks only to force Defendants to prove their substantiation, the FAC is nothing more than "undue harassment of advertisers," an impermissible private cause of action for lack of substantiation and should be dismissed. *King Bio*, 107 Cal. App. 4th at 1338.

### C. The FAC'S Allegations About The Study Flatly Contradict The Study Itself And Are Not Plausible.

Even if Plaintiff could bring its claims, these claims are not plausible and fail as a matter of law. The FAC is based on an attack of the validity of Defendants' study on which the 682% claim is based, containing conclusory allegations claiming that the tests are "flawed," "false, misleading, and reasonably likely to deceive the public." In support, the FAC makes specific allegations about what the study says and claims. However, these allegations are not plausible. In each and every material case, they are directly contrary to what the study actually says.

#### 1. The Court may properly consider the contents of the study in deciding a Rule 12(b)(6) motion because the study is an integral document to the FAC.

Although a court's analysis on a Rule 12(b)(6) motion is generally limited to the contents

of the complaint, a court may nevertheless consider materials "attached to the complaint as an exhibit or incorporated in it by reference . . . , matters of which judicial notice may be taken . . . , or documents either in plaintiff['s] possession or of which plaintiff[] had knowledge and relied in bringing suit." *Adams v. Crystal City Marriott Hotel*, No. 02-Civ. 10258, 2004 WL 744489, *3 (S.D.N.Y. Apr. 6, 2004) (quoting *Brass v. Am. Film Techs., Inc.*, 987 F.2d 142, 150 (2d Cir. 1993)). A court may also consider documents that are integral to a complaint's allegations. "Even where a document is not incorporated by reference, the court may nevertheless consider it where the complaint relies heavily upon its terms and effect, which renders the document 'integral' to the complaint." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (citation omitted); *see also I. Meyer Pincus & Assoc., P.C. v. Oppenheimer & Co., Inc.*, 936 F.2d 759, 762 (2d Cir. 1991) (indicating that a plaintiff cannot "evade a properly argued motion to dismiss simply because plaintiff has chosen not to attach [an integral document] or to incorporate it by reference"); *see also Dichter-Mad Family Partners, LLP v. United States*, 709 F.3d 749, 762 (9th Cir. 2013) ("Generally, the Court's analysis is limited to the contents of the complaint. However, '[w]hen a plaintiff has attached various exhibits to the complaint, those exhibits may be considered in determining whether dismissal [i]s proper.' Likewise, the Court 'may . . . consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment.'" (citations omitted)).

As set forth below, in pleading its causes of action, the FAC consist of a series of specific references to a study and its supporting documents that are integral documents to the FAC, are incorporated by reference, and may be considered without converting this Rule 12(b)(6) motion to a motion for summary judgment.

**2. The FAC fails to state plausible facts because these facts are directly contradicted by the actual study documents.**

Examining Defendants' study referenced in the FAC shows that Plaintiff has not stated plausible facts that can negate the veracity of Defendants' 682% increase in HGH levels claim. *See DuFour v. Allen*, No. 2:14–cv–05616–CAS (SSx, 2014 WL 4679098, at *1 n. 1 (C.D.Cal.

Sept. 15, 2014) (quoting *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001) ("Though a court must accept as true all material allegations in the complaint when considering a Rule 12(b)(6) motion, 'a court need not . . . accept as true allegations that contradict matters properly subject to judicial notice or by exhibit.'"). Plaintiff's entire attack against Defendants' 682% claim hinges on false statements about the study—false statements that are evidenced merely by reviewing the study that Plaintiff references. The FAC asserts that Defendants' study is "riddled with so many flaws that it is completely unreliable." [FAC, ¶ 14]. However, as demonstrated below, each and every one of the purported flaws pointed to by the FAC is demonstrably false when compared with the contents of the actual study.[3]

> **Allegation #1:**
>
> The test subjects' baseline growth hormone levels were much lower than the placebo group at the beginning of the test. Because the test group's HGH levels were so low, it would be expected that they would rise more than the placebo group and any result showing this would have been due to the imbalance between the two groups rather than SeroVital. There were no apparent adjustments made to correct for this imbalance. [FAC, ¶ 14.]

This allegation is not plausible or accurate. A review of the data surrounding the study shows no imbalance issue. The Study Poster on Defendants' website (referenced in the FAC)[4] and the Clincaltrials.gov SeroVital Publication describing the study, both point out that this was a "cross-over" study. *See* SeroVital Publication (attached as Exhibit 1 to the Declaration of Amy Heaton ("Heaton Decl.")), under "METHODS," and Clincaltrials.gov SeroVital Publication (Heaton Decl., Exhibit 2, at p. 1) under "Study Design." In a crossover experiment, the subjects are divided randomly into two groups, one of the groups is given tested treatment and the other one is given the placebo, and then the groups are interchanged until every subject has received both the control and the treatment. *See* the entry "CROSSOVER DESIGN" on the clinicaltrails.gov

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[3] For sake of clarity and convenience, Defendants have divided the FAC's allegations regarding the study into nine discrete, specific alleged facts and will address each one in turn. These nine items constitute the entirety of the FAC's factual allegations concerning the study and are quoted verbatim from the FAC.

[4] Contrary to the FAC, these representations do not appear on Sanmedica's website. However, the Study Poster that the FAC refers to does appear on the website for a similar product named SeroVital®, which is distributed by a different company, Novex Biotech, LLC.

website, http://clinicaltrials.gov/ct2/about-studies/glossary#C (Heaton Decl., Exhibit 6). Thus, there is no imbalance because the study subjects served as their own controls, and the study design, by its nature, adjusted for any possible imbalance by the nature of its crossover methodology

**Allegation #2:**

> Defendants falsely represent that the study results demonstrated a 682% mean increase in serum HGH levels. Even if a 682% mean increase in serum HGH levels was accurately reported despite the multitude of study design flaws, the 682% only represents a within-group result that does not account for the statistical significance of the comparative placebo results, and, thereby, necessarily attributes inflated results to SeroVital. [FAC, ¶ 14.]

If one looks at the actual study results that Plaintiff references, it is plain that the numbers Defendants reported from the study are actually conservative, not "false" or "inflated." The trial results showed that mean growth hormone increased 682% after the supplement from 0.17 ng/ml at baseline to 1.33 ng/ml at 120 minutes compared to a mean decrease of 52% after the placebo from 0.93 ng/ml to 0.45 ng/ml. *See* SeroVital Publication (Heaton Decl., Exhibit 1) under "RESULTS." Had Defendants opted to use the greatest mean effect in describing the results, the study would have found mean HGH to have increased by an average 734% over placebo, since the placebo group's HGH actually fell by a mean 52%. *Id.* Therefore, the within-group response is a more conservative value, reflective of the actual response over time, and is by no means an "inflated" or even the maximum claim that could accurately be made from the data. Plaintiff's conclusory allegations of falsity and inflation are contradicted by the study and, therefore, not plausible.

**Allegation #3:**

> The SeroVital study results were also flawed due to other confounding factors for which no controls were put into place by the researchers including, but not limited to, (1) failing to control for the amount of exercise that each subject engaged in, when exercise is known to be a potent stimulator of growth hormones . . . . [FAC, ¶ 15.]

The actual study documents reveal that this is not an issue. All subjects were fasting from 9:00

p.m. the prior night and came directly to the metabolic unit after waking in the morning. Thus, it is unlikely that any of the subjects could have exercised before the experiment. *See* SeroVital Publication (Heaton Decl., Exhibit 1) under "METHODS," and Clincaltrials.gov SeroVital Publication (Heaton Decl., Exhibit 2) ("Each subject reported to the Inpatient Unit on two occasions one week apart. After an overnight fast, subjects had an IV line placed and baseline bloods samples were drawn at -30, -15, and 0 minutes. Subjects were then asked to swallow the capsules of supplement (Setovital™) to an identical looking placebo . . . Blood was drawn at 15, 30, 60, and 90 and 120 minutes for assay"). Furthermore, even if some of the participants could have exercised, the study had its own built in control for this. As already discussed above, the study was a crossover study, so the control group and the study group were the same people, serving as their own controls over time. *See* SeroVital Publication (Heaton Decl., Exhibit 1), , under "METHODS" and Clincaltrials.gov SeroVital Publication (Heaton Decl., Exhibit 2 at p. 1) under "Study Design."

**Allegation #4:**

> The SeroVital study results were … flawed due to other confounding factors for which no controls were put into place by the researchers including, but not limited to, … (2) failing to control the time of day the placebo and SeroVital blood samples were taken, when it is known that growth hormone is released by the pituitary gland in bursts. If the blood samples were taken at different times of the day when the placebo and SeroVital 9 supplement were ingested, SeroVital ingestion may well have been at those times that growth hormone was being naturally secreted by the anterior pituitary gland; and, in contrast, the placebo ingestion could have been at the time of the day when growth hormone levels were being lowered naturally. Thus, no confidence can be placed on the results without knowing the times of the day when the samples were taken, which the study tellingly omits. [FAC, ¶ 14.]

The actual study documents again demonstrate that this allegation is false. As the study documents show, all subjects were fasting from the prior night and came directly to the metabolic unit after waking in the morning. *See* SeroVital Publication (Heaton Decl., Exhibit 1) under "METHODS" ("Each subject reported to the Inpatient Unit on two occasions one week apart. After an overnight fast, subjects had an IV line placed and baseline bloods samples were drawn at -30, -15, and 0 minutes. Subjects were then asked to swallow the capsules of supplement

(Setovital™) to an identical looking placebo . . . Blood was drawn at 15, 30, 60, and 90 and 120 minutes for assay").

**Allegation #5:**

> Defendants do not rely on a study ***report*** of the type that would be accepted by any credible, peer-reviewed scientific journal. Rather, Defendants rely on a published study ***abstract*** and, even then, the "abstract" published on Defendants' web site materially enhances what is stated in the published abstract. Moreover, published abstracts – as opposed to reports – are not peer-reviewed and are not relied on by the scientific community unless subsequently published in a full final report in a peer reviewed journal. The SeroVital study abstract also does not identify who funded the study—a strong indicator of potential bias. [FAC, ¶ 16.]

This is contradicted by the facts surrounding the study, which show that the study is relied on by the scientific community. For example, pilot studies on the mechanism and clinical applications of SeroVital have been conducted, submitted, and accepted for presentation at academic conferences for both the Obesity Society and the Pituitary Society. *See* acceptance letters and posters (Heaton Decl., Exhibits 3, 4, and 5). Given this acceptance and other scientific controls (including double-blind), not knowing the source of funding cannot, by itself, create even an inference of falsity.

**Allegation #6:**

> Further, although the study abstract reports results of 16 study participants, there is no mention of the total number of participants enrolled in the study. Thus, there is no way to determine whether these 16 participants represent the whole study or whether data was improperly mined to arrive at a desired result. [FAC, ¶ 17.]

The study data shows that exactly 16 subjects were enrolled and completed the study. There were no drop-outs and all subjects were included in the data analysis. *See* Clincaltrials.gov SeroVital Publication (Heaton Decl., Exhibit 2 at p. 2) under "Inclusion Criteria" ("12 healthy males and 4 healthy females"); and SeroVital Publication (Heaton Decl., Exhibit 1) under "METHODS" ("This cross-over, placebo controlled, double-blind study involved 16 healthy subjects").

**Allegation #7:**

> And, no mention is made of what statistical technique was used to analyze the data such that the results cannot be independently confirmed. [FAC, ¶ 17.]

This allegation is directly contradicted by the SeroVital Publication on Defendants' website (referenced by the FAC at ¶ 17), describing the statistical methods and results, including the P Values. *See* SeroVital Publication (Heaton Decl., Exhibit 1) under "Results" ("After 120 minutes, GH levels had increased 8-fold from baseline (0.17 to 1.33ng/ml) and were significantly higher mean AUC was observed after taking the supplement [20.4 (95% CI: 19.9-21.0ng/ml) vs. 19.7 (95% CI: 18.7-20.6NG/ML); p=0.04]" and "The mean change in GH levels from baseline to 120 minutes (GH at 120 minutes minus GH at 0 minutes), was 1.15 (95% CI: 0.17, 2.14) ng/ml after the supplement versus -0.48 (-1.47, 0.50) ng/ml after the placebo, demonstrating a statistically significant differential effect (P=0.01). After the supplement, the mean AUC for GH across 120 minutes was 20.43 (95% CI: 19.90, 20.95) ng/ml/min which was significantly higher (P=0.40) than placebo at 19.67 (18.74, 20.59) ng/ml/min").

**Allegation #8:**

> Finally, and significantly, Defendants fail to accurately represent the actual study abstract on their website. Defendants falsely represent that the SeroVital study abstract does not indicate that it was double-blinded—a fact, that if it exists, is routinely mentioned. [FAC, ¶ 17.]

The study was, in fact, double blinded. *See* Clincaltrials.gov SeroVital Publication (Heaton Decl., Exhibit 2 at p. 1) under "Study Design:" ("Masking: Double Blind (subject, Investigator)") and SeroVital Publication (Heaton Decl., Exhibit 1) under "METHODS" ("This cross-over, placebo controlled, double-blind study involved 16 healthy subjects").

**Allegation #9:**

> [The study] is absolutely not evidence of the "associated" benefits it did not even test. [FAC, 17].

Pilot studies on the mechanism and clinical applications of SeroVital have been conducted, submitted, and accepted for presentation at academic conferences for both the Obesity Society and the Pituitary Society. *See* acceptance letters and posters (Heaton Decl., Exhibits 3, 4, and 5). In addition, as admitted in the FAC, Defendants' advertising does not claim these associated benefits have been tested; only that they are associated with peak growth hormone levels. The FAC does not allege that this association is false.

In summary, when one examines the actual study documents that the FAC references, and which are integral to it, all of Plaintiff's alleged facts about the study are rendered false and implausible. Such allegations cannot form a basis for attacking the veracity of the study, leaving the FAC without any "facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. Plaintiff's FAC, therefore, should be dismissed for failure to state a plausible claim for relief.

### 3. The FAC Fails To Show That Defendants Did Not Rely On Competent And Reliable Scientific Evidence.

Even if Plaintiff could bring its private claims and these claims were somehow plausible (despite their direct contradictions to the integral study documents upon which they were based), the FAC would still fail as a matter of law because of the glaring omission of factual allegations showing Defendants failed to rely on competent and reliable scientific evidence.

In order to have a "reasonable basis" (*i.e.*, substantiation) to make "clinically shown" claims, an advertiser must possess "competent and reliable scientific evidence." *FTC v. Lane Labs-USA, Inc., No.* 00-CV-3174, 2007 WL 316462, at *1 (D.N.J. Jan. 30, 2007), *vacated on other grounds*, 626 F.3d 575, 584-85 (3d Cir. 2010) (affirming district court's holding that competent and reliable scientific evidence supported "clinically proven" and "clinically shown" claims for calcium supplement); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F.Supp.2d 285, 299 (D. Mass. 2008) ("For health-related efficacy and safety claims, the FTC has commonly insisted on 'competent and reliable scientific evidence.'") (citing cases), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *FTC v. Nat'l Urological Group, Inc.*, 645 F.Supp.2d 1167, 1186 (N.D. Ga. 2008) ("The FTC requires advertising claims that pertain to a health benefit to be substantiated by competent and reliable scientific evidence."). The "reasonable basis" standard has held sway for nearly 40 years. *See In re Pfizer, Inc.*, 81 FTC 23 (1972).

Defendants possessed a reasonable basis (competent and reliable scientific evidence) to make those claims – and still do:

> "Competent and reliable scientific evidence" is defined as: Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and

> evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

*FTC v. Chinery*, No. 05-3460, 2006 WL 3878416, at *3 (D.N.J. Dec. 26, 2006). "This is the same standard the FTC applies to any industry making health-related claims." *See* FTC, Dietary Supplements: An Advertising Guide for Industry, 9 (April 2001) (hereinafter "FTC Guide"), as Exhibit 1 to Defendants' Request for Judicial Notice ("RJN"), filed herewith.

In fact, under a FTC Consent Order Defendants are under a clear and explicit standard dictating the requirements allowing Defendants to make claims about their products. The FTC Consent Order dictates:

> **IT IS FURTHER ORDERED** … shall not make any representation… unless at the time the representation is made respondents possess and rely upon ***a reasonable basis*** for the representation, ***which shall consist of competent and reliable scientific evidence***.

RJN, Exhibit 2 at p. 3 (emphasis added).

The Consent Order also explicitly defines what qualifies as "competent and reliable scientific evidence:"

> "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, ***or*** other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

*Id.*, at p. 2 (emphasis added).

In a recent court order granting a motion for partial summary judgment in a case brought by Defendants and associated entities against the FTC, a federal judge in the District of Utah ordered that this "reasonable basis" standard applies to Defendants, "is clear and unambiguous," and no additional requirements may be added to it. *See* RJN, Exhibit 3. In the same Order, Judge Waddoups also held that "the FTC Order may be enforced only according to its terms." *Id.*

Thus, by law Defendants are simply not under the obligation to base advertising claims on the type of iron-clad, flawless, and indisputable evidence that the FAC alleges Defendants fail to live up to. In fact, based on the clear language of the Consent Order (also as applied by the

District Court), Defendants are not even required to have a study at all to provide a reasonable basis for product claims. Instead, all Defendants need is "evidence," which can include "tests, analyses, research, studies, ***or*** other evidence." RJN, Exhibit 1 at p. 10 (emphasis added) ("there is no requirement that a dietary supplement claim be supported by any specific number of studies"); *See also* RJN, Exhibit 2 at p. 2

As Judge Easterbrook explained in *FTC v. QT, Inc.*, even something less than a gold standard study may suffice to support a health claim. 512 F.3d 858, 861 (7th Cir. 2008) ("nothing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies . . . Placebo-controlled, double-blind testing is not a legal requirement for consumer products."); *see also* FTC Guide, at 9. What is clear, however, is that the "competent and reliable scientific evidence" substantiation standard for advertising claims ***does not*** require "uncontroverted evidence." *FTC v. Garden of Life, Inc.*, 845 F. Supp. 2d 1328 (2012), *aff'd in part, vacated in part, remanded by,* 516 Fed. Appx. 852 (11th cir. 2013) (finding that advertising claims for defendants' calcium supplement were substantiated even though FTC's expert concluded to the contrary). In other words, there is room for disagreement between experts as to whether a claim is substantiated without that claim necessarily being found to be false.

The FAC simply fails to even allege facts showing that Defendants lack "evidence," as defined by the Consent Order and by the District Court Order. The FAC fails to even allege that the study is anything other than a study based on the expertise of professionals in the relevant area. The FAC fails to allege any plausible facts showing that the study has not been conducted in an objective manner by persons qualified to do so. The FAC fails to allege plausible facts claiming that the study did not use procedures generally accepted in the profession to yield accurate and reliable results. Finally, the FAC fails to even allege that Defendants do not rely on any additional tests, analyses, research, studies, or other evidence that meet these criteria. Plaintiff has not pled such facts because it cannot do so. While Plaintiffs may disagree with the adequacy of the scientific evidence, that is simply legally insufficient to render the challenged claims unsubstantiated and certainly not enough to demonstrate that the claims are actually false or misleading. In short, nothing in the FAC alleges facts sufficient to show that the advertising

claims are not supported by competent and reliable scientific evidence. Therefore, the FAC fails to state a claim as a matter of law and should be dismissed.

## IV. CONCLUSION

For the foregoing reasons, the Motion to Dismiss should be granted without leave to amend.

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